As Filed Pursuant to Rule 424(b)(3)
Registration No. 333-264231
Registration No. 333-264465

Prospectus Supplement No. 1
(To Prospectus dated April 25, 2022)

27,270,720 Units consisting of Common Stock or Pre-Funded Warrants to Purchase Common Stock and Class A Warrants to Purchase Common Stock

This prospectus supplement updates and supplements the prospectus dated April 25, 2022 (the "**Prospectus**"), which forms a part of our Registration Statement on Form S-1, as amended (Registration No. 333-264231) and our additional Registration Statement on Form S-1 (Registration No. 333-264465) filed pursuant to Rule 462(b) promulgated under the Securities Act of 1933, as amended (the "**Securities Act**") (collectively, the "**Registration Statements**"). This prospectus supplement is being filed to update and supplement the information in the Prospectus with the information contained in our Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 16, 2022 (the "**Quarterly Report on Form 10-Q**"). Accordingly, we have attached the Quarterly Report on Form 10-Q to this prospectus supplement.

The Prospectus and this prospectus supplement relate to the issuance by us of an aggregate of 27,270,720 Units consisting of one share of our common stock, par value $0.0001 per share (the "**Common Stock**"), or one pre-funded warrant in lieu thereof, and one Class A Warrant to purchase one share of Common Stock.

The Prospectus and this prospectus supplement also relate to the issuance by us of the Common Stock issuable from time to time upon exercise of the Class A Warrants and pre-funded warrants offered pursuant to the Registration Statements.

This prospectus supplement should be read in conjunction with the Prospectus as amended and supplemented to date. This prospectus supplement updates and supplements the information in the Prospectus. If there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

The Common Stock is listed on the Nasdaq Global Market ("**Nasdaq**") under the symbol "CRXT." The last reported sale price of the Common Stock on Nasdaq on May 13, 2022 was $0.458 per share.

There is no established trading market for the pre-funded warrants or Class A Warrants and we do not expect an active trading market to develop. We do not intend to list the pre-funded warrants or the Class A Warrants on any securities exchange or other trading market. Without an active trading market, the liquidity of these securities will be limited.

Investing in our securities involves risks. See "*Risk Factors*" beginning on page 7 of the Prospectus before you make an investment in our securities.

Neither the U.S. Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of the Prospectus or this prospectus supplement. Any representation to the contrary is a criminal offense.

Maxim Group LLC

Prospectus Supplement dated May 16, 2022.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-39802

CLARUS THERAPEUTICS HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**85-1231852**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
555 Skokie Boulevard, Suite 340 Northbrook, Illinois	**60062**
(Address of principal executive offices)	**(Zip Code)**

(847) 562-4300
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common stock, par value $0.0001 per share	**CRXT**	**The Nasdaq Stock Market LLC**
Warrants to purchase one share of common stock at an exercise price of $11.50 per share	**CRXTW**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer, "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 11, 2022, there were 52,020,731 shares of common stock, par value $0.0001 per share, issued and outstanding.

CLARUS THERAPEUTICS HOLDINGS, INC.
Quarterly Report on Form 10-Q

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In this Quarterly Report on Form 10-Q, unless otherwise stated or as the context otherwise requires, references to "Clarus," "Clarus Therapeutics," "Clarus Therapeutics Holdings," "the Company," "we," "us," "our" and similar references refer to Clarus Therapeutics Holdings, Inc. together with its consolidated subsidiary. The Clarus Therapeutics logo, JATENZO and other trademarks of Clarus Therapeutics Holdings, Inc. appearing in this Quarterly Report on Form 10-Q are the property of Clarus Therapeutics Holdings, Inc. This Quarterly Report on Form 10-Q also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing herein are the property of their respective holders.

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains express or implied forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. Forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our ability to obtain funding for our operations and to grow our business;
- our ability to successfully commercialize and market JATENZO and any future product candidates, if approved, and the timing of any commercialization and marketing efforts;
- the potential market size, opportunity and growth potential for JATENZO and any future product candidates, if approved;
- the benefits of testosterone, or T, replacement therapy in certain populations, patients' drug administration preferences and acceptance of JATENZO by physicians and patients;
- our plans and expectations regarding our strategic alternative review process and the timing and success of such process regarding a potential transaction;
- the timing of our product development activities and the initiation, timing, progress and results of our exploratory trials and studies to guide the development of JATENZO for additional potential indications;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- expectations regarding sales of JATENZO and the costs of supplying, manufacturing and continuing to commercialize JATENZO;
- our ability to obtain marketing approval and acceptance for JATENZO in territories outside of the United States;
- our ability to maintain the listing of our common stock on the Nasdaq Global Market and the potential liquidity and trading of our securities;
- our future financial performance and expectations regarding future expenditures;
- the accuracy of our estimates regarding expenses, capital requirements and our future needs for additional financing;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professional;
- developments relating to our competitors and our industry, and our ability to compete effectively in a competitive industry;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately and to produce sufficient quantities of clinical and potentially future commercial supplies;
- our ability to enter into marketing or co-promotional arrangements and strategic partnerships;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- regulatory, judicial, and legislative developments and their impact on our business;
- the impact from the outcome of any known and unknown litigation; and
- other risks and uncertainties, including those listed under the section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, or the 2021 Annual Report.

The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements reflect our current views with respect to future events, are based on assumptions and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, without limitation:

- We have incurred significant operating losses and there is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail our operations. We will need to raise additional capital to support our operations. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital or address our liquidity needs may force us to delay, limit or terminate our operations, make reductions in our workforce, discontinue our commercialization efforts for JATENZO as well as other development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code.
- We have significant indebtedness and servicing our debt requires a significant amount of cash. We may not have sufficient cash flow from our operations to satisfy the financial covenants in our debt agreements. We may not receive a waiver of default for outstanding indebtedness for which we may be in default in the future.
- We may not be successful in identifying and implementing any strategic business combination or other transaction and any strategic transactions that we may consummate in the future could have negative consequences.
- JATENZO is the only product we are commercializing. If we fail to successfully commercialize JATENZO, we may need to acquire additional product candidates and our business may be impaired.
- We have limited experience as a commercial company and the marketing and sale of JATENZO or any future approved drugs may be unsuccessful or less successful than anticipated.
- Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.
- Our reliance on third-party suppliers and distributors could harm our ability to commercialize JATENZO or any product candidates that may be approved in the future.
- The ongoing COVID-19 pandemic is having, and is expected to have, an adverse impact on our business.
- The U.S. Food and Drug Administration, or FDA, and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.
- Even though we have received marketing approval for JATENZO in the United States, we may never receive marketing approval outside of the United States, or receive pricing and reimbursement outside the United States at acceptable levels.
- Recent federal legislation may increase pressure to reduce prices of certain pharmaceutical products paid for by Medicare, which could materially adversely affect our revenue and our results of operations.
- Testosterone is a Schedule III (non-narcotic) substance under the Controlled Substances Act and any failure to comply with this Act or its state equivalents would have a negative impact on our business.
- If coverage and reimbursement for JATENZO are limited, it may be difficult for us to profitably sell JATENZO.
- Our market is subject to intense competition. If we are unable to compete effectively, our opportunity to generate revenue from the sale of JATENZO will be impaired.
- If we are unable to obtain or protect intellectual property rights related to JATENZO, we may not be able to compete effectively in our market.
- We may be involved in lawsuits and proceedings to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.
- We have identified material weaknesses in our internal control over financial reporting, and we may identify future material weaknesses in our internal control over financial reporting.
- We will need to grow our company, and we may encounter difficulties in managing this growth, which could disrupt our operations.

- Our future success depends on our ability to retain our chief executive officer, chief financial officer and chief commercial officer and to attract, retain and motivate qualified personnel.
- Our debt agreements contain restrictions that limit our flexibility in operating our business.

Additional discussion of the risks, uncertainties and other factors described above, as well as other risks and uncertainties material to our business, can be found under “Risk Factors” in the 2021 Annual Report and we encourage you to refer to that additional discussion. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our plans, objectives, estimates, expectations and intentions only as of the date of this filing. You should read this report completely and with the understanding that our actual future results and the timing of events may be materially different from what we expect, and we cannot otherwise guarantee that any forward-looking statement will be realized. We hereby qualify all of our forward-looking statements by these cautionary statements.

Except as required by law, we undertake no obligation to update or supplement any forward-looking statements publicly, or to update or supplement the reasons that actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. You are advised, however, to consult any further disclosures we make on related subjects.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

CLARUS THERAPEUTICS HOLDINGS, INC.
Condensed Consolidated Balance Sheets (unaudited)
(in thousands, except share and per share data)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 9,137	$ 26,415
Accounts receivable, net	8,005	6,341
Inventory, net	14,930	14,214
Prepaid expenses	4,383	4,673
Total current assets	36,455	51,643
Property and equipment, net	67	65
Total assets	$ 36,522	$ 51,708
Liabilities and stockholders' deficit		
Current liabilities:		
Senior notes payable	$ 38,485	$ 42,269
Accounts payable	14,056	13,945
Accrued expenses	11,433	8,261
Deferred revenue	1,980	1,585
Total current liabilities	65,954	66,060
Derivative warrant liability	925	1,567
Total liabilities	66,879	67,627
Commitments and contingencies (See Note 12)		
Stockholders' deficit:		
Preferred stock $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	—	—
Common stock $0.0001 par value; 125,000,000 shares authorized; 24,750,011 and 24,025,817 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	306,166	305,734
Accumulated deficit	(336,525)	(321,655)
Total stockholders' deficit	(30,357)	(15,919)
Total liabilities and stockholders' deficit	$ 36,522	$ 51,708

The accompanying notes are an integral part of these unaudited condensed financial statements.

CLARUS THERAPEUTICS HOLDINGS, INC.
Condensed Consolidated Statements of Operations (unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2022	2021
Net product revenue	$ 4,011	$ 2,330
Cost of product sales	664	367
Gross profit	3,347	1,963
Operating expenses:		
Sales and marketing	10,729	7,937
General and administrative	5,285	3,605
Research and development	881	1,210
Total operating expenses	16,895	12,752
Loss from operations	(13,548)	(10,789)
Other income (expense), net:		
Change in fair value of warrant liability	642	—
Interest income	1	—
Interest expense	(1,965)	(4,640)
Total other expense, net	(1,322)	(4,640)
Net loss before income taxes	(14,870)	(15,429)
Provision for income taxes	—	—
Net loss	(14,870)	(15,429)
Accretion of preferred stock	—	(3,939)
Net loss attributable to common stockholders – basic and diluted	$ (14,870)	$(19,368)
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.61)	$ —
Weighted-average common shares used in net loss per share attributable to common stockholders, basic and diluted	24,202,842	—

The accompanying notes are an integral part of these unaudited condensed financial statements.

CLARUS THERAPEUTICS HOLDINGS, INC.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit (unaudited)
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	—	$ —	24,025,817	$ 2	$ 305,734	$ (321,655)	$ (15,919)
Issuance of shares in connection with exercise of pre-funded warrants	—	—	724,194	—	—	—	—
Stock-based compensation	—	—	—	—	432	—	432
Net loss	—	—	—	—	—	(14,870)	(14,870)
Balance at March 31, 2022	—	$ —	24,750,011	$ 2	$ 306,166	$ (336,525)	$ (30,357)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	36,756,498	$ 198,195	870,263	$ 1	$ —	$ (325,781)	$ (325,780)
Retroactive application of the recapitalization due to the Business Combination (Note 3)	—	—	(870,263)	(1)	—	1	—
Adjusted balance at December 31, 2020	36,756,498	198,195	—	—	—	(325,780)	(325,780)
Conversion of convertible notes payable into Series D redeemable convertible preferred stock	747,451	3,360	—	—	—	—	—
Conversion of Series D redeemable convertible preferred stock into common stock (1)	(2,630,585)	(11,829)	—	—	11,829	—	11,829
Accretion of redeemable convertible preferred stock to redemption value (1)	—	3,939	—	—	(3,939)	—	(3,939)
Stock-based compensation	—	—	—	—	176	—	176
Net loss	—	—	—	—	—	(15,429)	(15,429)
Balance at March 31, 2021	34,873,364	$ 193,665	—	$ —	$ 8,066	$ (341,209)	$ (333,143)

The accompanying notes are an integral part of these unaudited condensed financial statements.

(1) Relates to activity associated with the Redeemable Convertible Preferred Stock prior to the reverse recapitalization on September 9, 2021. As all common shares have been retroactively restated to give effect to the Business Combination, there are no shares of common stock associated with the conversion of Series D redeemable convertible preferred stock.

CLARUS THERAPEUTICS HOLDINGS, INC.
Condensed Consolidated Statements of Cash Flows (unaudited)
(in thousands)

	Three Months Ended March 31,	
	2022	2021
Operating activities		
Net loss	$(14,870)	$(15,429)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense related to debt financing and royalty obligation, net of payments	(3,785)	4,640
Change in fair value of warrant liability	(642)	—
Stock-based compensation expense	432	176
Depreciation	7	5
Changes in operating assets and liabilities:		
Accounts receivable	(1,664)	(825)
Inventory	(716)	(2,177)
Prepaid expenses	290	(275)
Accounts payable	111	4,082
Accrued expenses	3,173	2,839
Deferred revenue	396	(78)
Net cash used in operating activities	(17,268)	(7,042)
Investing activities		
Purchases of property and equipment	(10)	(11)
Net cash used in investing activities	(10)	(11)
Financing activities		
Proceeds from issuance of convertible notes payable	—	7,184
Net cash provided by financing activities	—	7,184
Net (decrease) increase in cash and cash equivalents	(17,278)	131
Cash and cash equivalents – beginning of period	26,415	7,233
Cash and cash equivalents – end of period	$ 9,137	$ 7,364
Supplemental disclosure of non-cash investing and financing activities:		
Accretion of redeemable convertible preferred stock to redemption value, including dividends on preferred stock	$ —	$ 3,939
Conversion of convertible notes payable into Series D redeemable convertible preferred stock	$ —	$ 3,360
Conversion of Series D redeemable convertible preferred stock into common stock	$ —	$ 11,829
Cash paid for interest	$ 5,750	$ —

The accompanying notes are an integral part of these unaudited condensed financial statements.

1. Organization and Description of Business Operations

Clarus Therapeutics Holdings, Inc. (together with its consolidated subsidiary, the "Company" or "Clarus") formerly known as Blue Water Acquisition Corp. ("Blue Water"), was incorporated in Delaware on May 22, 2020 as a special purpose acquisition company ("SPAC") formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses.

The registration statement for the Company's Initial Public Offering ("IPO") was declared effective on December 15, 2020. On December 17, 2020, the Company consummated its IPO of 5,750,000 units (each unit representing a share of common stock and a warrant to purchase a share of common stock ("IPO warrants")), including 750,000 additional Units to cover over-allotments, at $10.00 per unit, generating gross proceeds of $57.5 million, and incurring offering costs of approximately $3.7 million, of which approximately $2.0 million was for deferred underwriting commissions. Simultaneously with the closing of the IPO, the Company consummated the private placement ("Private Placement") of 3,445,000 warrants (each, a "Private Placement Warrant" and collectively, the "Private Placement Warrants") at a price of $1.00 per Private Placement Warrant to Blue Water Sponsor LLC (the "Sponsor"), generating proceeds of approximately $3.4 million. Upon the closing of the IPO and the Private Placement, approximately $58.7 million ($10.20 per Unit) of the net proceeds of the IPO and certain of the proceeds of the Private Placement was held in a trust account ("Trust Account") located in the United States with Continental Stock Transfer & Trust Company acting as trustee, and were invested only in U.S. "government securities" within the meaning of Section 2(a)(16) of the U.S. Investment Company Act of 1940, as amended (the "Investment Company Act") having a maturity of 185 days or less or in money market funds meeting certain conditions under Rule 2a-7 promulgated under the Investment Company Act, which invested only in direct U.S. government treasury obligations, as determined by the Company, until the earlier of: (i) the completion of a business combination and (ii) the distribution of the Trust Account.

In December 2021, the Company issued and sold 3,024,194 units in a private placement at a purchase price of $4.96 per unit, resulting in net proceeds of $13.8 million, after deducting offering expenses. Each unit consisted of one share of common stock (or one pre-funded warrant in lieu thereof), and a five-year warrant to purchase one share of common stock at an exercise price of $5.25 per share. In connection with the private placement, the Company filed a resale registration statement with the Securities and Exchange Commission (the "SEC") in December 2021 to register the resale of the common stock by the purchaser in the private placement.

Merger

On September 9, 2021 (the "Closing Date"), the Company, and Blue Water Merger Sub Corp., a Delaware corporation and wholly-owned subsidiary of the Company ("Merger Sub"), consummated the previously announced merger, pursuant to the Agreement and Plan of Merger, dated as of April 27, 2021 (the "Merger Agreement"), with Clarus Therapeutics, Inc., a Delaware corporation ("Legacy Clarus"), pursuant to which, subject to the terms and conditions set forth in the Merger Agreement, Merger Sub merged with and into Legacy Clarus, with Legacy Clarus surviving as a wholly-owned subsidiary of the Company, and with Legacy Clarus's equity holders' and convertible debt holders equity interests converted into the right to receive shares of the Company's common stock or else be cancelled, retired and terminated without consideration, as provided in the Merger Agreement (the "Merger"). Upon the consummation of the business combination, Blue Water changed its name to "Clarus Therapeutics Holdings, Inc."

In connection with the Merger, Legacy Clarus's convertible noteholders and senior secured noteholders provided $25.0 million in additional capital to Legacy Clarus following the announcement of the execution of the Merger Agreement. All such proceeds plus accrued interest converted to shares of the Company's common stock at a price of $10.00 per share, resulting in 2,549,939 shares issued on the Closing Date. The additional capital of $25.0 million was received by Legacy Clarus prior to the Closing Date. Together with Blue Water's cash resources and additional capital, the Company received net proceeds from the Merger (not including the $25.0 million of additional capital) of approximately $17.0 million.

At the effective time of the Merger (the "Effective Time"), shares of Legacy Clarus's Series D redeemable convertible preferred stock ("Series D Preferred Stock") issued and outstanding and all principal and accrued interest under Legacy Clarus's convertible notes immediately prior to the Effective Time converted into 13,431,410 shares of the Company's common stock at a price of $10.20 per share. Additionally, $10.0 million of debt related to Legacy Clarus' senior secured notes, including certain royalty rights was exchanged for an aggregate of 1,500,000 shares of the Company's common stock. Further, under a share allocation agreement entered into by Blue Water and Legacy Clarus on September 1, 2021, as part of the Merger, an additional 405,000 shares of the Company's common stock were allocated to the senior secured noteholders (as further described in Note 3, *Business Combination*, which included 270,000 shares reallocated to the senior secured note holders from Legacy Clarus's equity holders and 135,000 shares from the Blue Water founder that were transferred from the Sponsor pursuant to the share allocation agreement. All unexpired, outstanding Series D Warrants of Legacy Clarus remained outstanding and became exercisable for shares of the Company's common stock, subject to adjustment in accordance with the Merger exchange ratio.

All other series of Legacy Clarus preferred stock, common stock and stock options were cancelled and extinguished upon completion of the Merger. In addition, Legacy Clarus's existing equity incentive plans were terminated.

For additional information on the business combination, please refer to Note 3, *Business Combination*, to these condensed consolidated financial statements.

Description of Business Following the Merger

The Company operates as a pharmaceutical company post-merger focused on the commercialization of JATENZO® (testosterone undecanoate), the first and only oral testosterone ("T") replacement, or testosterone replacement therapy ("TRT"), of its kind approved by the U.S. Food and Drug Administration ("FDA"). The FDA approved JATENZO for marketing on March 27, 2019, and Legacy Clarus commercially launched JATENZO on February 10, 2020. JATENZO is the Company's sole source of revenue and sales are exclusively within the United States. Management remains committed to the product's commercial success. In parallel, the broader vision is for the Company to become a profitable pharmaceutical company initially focused on the development and commercialization of T and metabolic therapies for men and women. The Company was founded in 2004 and is located and headquartered in Northbrook, Illinois.

The Company is subject to risks and uncertainties associated with any pharmaceutical company that is transitioning from the development to commercial stage. Since inception, Legacy Clarus incurred substantial operating losses due to substantial product development and commercialization expenditures. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees and consultants. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of JATENZO, is cash flow positive from operations, or enters into cash flow positive business development transactions.

The Company's U.S. patent portfolio on JATENZO currently includes five issued patents and has recently received two notices of allowance from the United States Patent and Trademark Office ("USPTO") for claims that cover its oral testosterone replacement product, JATENZO. The issued U.S. patents contain claims to both pharmaceutical compositions and methods of treatment using the Company's proprietary pharmaceutical composition and all are listed in the FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. In addition, the Company has several patent applications pending in the United States and other countries that, if issued, will cover pharmaceutical compositions, methods of treatment and other features of JATENZO, and have the potential to extend patent coverage beyond 2030.

Liquidity and Going Concern

The Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued.

Since its inception, Legacy Clarus has devoted substantially all its efforts to business planning, clinical development, commercial planning and raising capital. Legacy Clarus, and since the Merger, the Company has incurred significant losses from operation since inception and has an accumulated deficit of $336.5 million as of March 31, 2022. Further, as of March 31, 2022, the Company had a working capital deficit of $29.5 million.

In addition to the consummation of the merger, the Company plans to seek additional funding through the expansion of its commercial efforts to grow JATENZO and its operating cash flow, business development efforts to out-license JATENZO internationally, equity financings, debt financings such as the secured notes described in Note 7, *Debt*, or other capital sources including collaborations with other companies or other strategic arrangements with third parties. There can be no assurance that these future financing efforts will be successful.

If the Company is unable to obtain funding or generate operating cash flow, the Company will be forced to delay, reduce, or eliminate some or all of its product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders.

Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, as of the issuance date of the condensed consolidated financial statements for the three months ended March 31, 2022, the Company has concluded that its cash and cash equivalents will not be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through at least twelve months from the date that these condensed financial statements are available to be issued and that there is substantial doubt about the Company's ability to continue as a going concern.

The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the condensed consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Impact of the COVID-19 Pandemic

The business disruptions associated with the ongoing COVID-19 pandemic had a significant negative impact on the Company's condensed consolidated financial statements for the three months ended March 31, 2022 and 2021. Management expects that the public health actions being undertaken to reduce the spread of the virus, and that may have to be undertaken again in the event the COVID-19 pandemic worsens, such as by the omicron variant or other variants that may surface, will create significant disruptions to the Company with respect to: (i) the

demand for its products, (ii) the ability of its sales representatives to reach healthcare customers, (iii) its ability to maintain staffing levels to support its operations, (iv) its ability to continue to manufacture certain of its products, (v) the reliability of its supply chain and (vi) its ability to achieve the financial covenants required by the senior secured notes agreement (see Note 7, *Debt*). The extent to which the ongoing COVID-19 pandemic will impact the Company's business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, vaccine rates and mandates, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The Company is closely monitoring the evolving impact of the pandemic on all aspects of its business. The Company has implemented a number of measures designed to protect the health and safety of its employees, support its customers and promote business continuity. The Company is also actively reviewing and implementing cost-saving measures including discontinuing or delaying all non-essential services and programs and instituting controls on travel, events, marketing and pre-clinical studies and clinical trials to adapt the business plan for the evolving COVID-19 challenges.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2021 and the notes thereto, which are included in the Form 10-K filed with the SEC pursuant on March 31, 2022 (the "2021 Form 10-K"). Since the date of those consolidated financial statements, there have been no material changes to its significant accounting policies, except as noted below.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three-month period ended March 31, 2022 are not necessarily indicative of the results that may be expected for the year ended December 31, 2022. The condensed consolidated balance sheet at December 31, 2021, has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. For further information, refer to the audited consolidated financial statements and footnotes thereto included in the 2021 Form 10-K.

As a result of the Merger, the shares and corresponding capital amounts and loss per share related to Legacy Clarus' outstanding common stock prior to the Merger have been retroactively restated to reflect the actual shares for which the common stock converted into as a result of the conversion terms in the Merger Agreement. For additional information on the Business Combination, please refer to Note 3, *Business Combination*, to these condensed consolidated financial statements.

Revenue Recognition

In accordance with Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606"), an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to be entitled to in exchange for those goods or services. The Company performs the following five steps to recognize revenue under ASC 606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only recognizes revenue when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that will be transferred to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. The Company has determined that the delivery of its product to its customer constitutes a single performance obligation as there are no other promises to deliver goods or services. Shipping and handling activities are considered fulfillment activities and are not considered to be a separate performance obligation. The Company has assessed the existence of a significant financing component in the agreements with its customers. The trade payment terms with its customers do not exceed one year and therefore, no amount of consideration has been allocated as a financing component. Taxes collected related to product sales are remitted to governmental authorities and are excluded from revenue.

Net Product Sales

The Company began selling JATENZO in February 2020, in the United States through a third party licensee which takes title and control of the goods. The third party licensee distributes the product to wholesale distributors (collectively the "Distributors"), with whom the Company has entered into formal agreements for delivery to retail pharmacies. The Company has also entered into arrangements with payors that provide government mandated and/or privately negotiated rebates, chargebacks and discounts for the purchase of the Company's products.

The Company recognizes revenue on sales of JATENZO when the customer obtains control of the product, which occurs at a point in time, typically upon delivery. Product revenues are recorded at the product's wholesale acquisition costs, net of applicable reserves for variable consideration that are offered within contracts between the Company and its customers, wholesale distributors, payors, and other indirect customers relating to the sale of JATENZO. Components of variable consideration include government and commercial contract rebates, product returns, chargebacks, commercial co-payment assistance program transactions and distribution services fees. These deductions are based on the amounts earned or to be claimed on the related sales and are classified as a current liability or reduction of receivables, based on expected value method and a range of outcomes and are probability weighted in accordance with ASC 606.

The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognition under contracts will not occur in a future period. The Company's analyses contemplate the application of the constraint in accordance with ASC 606. Actual amounts of consideration ultimately received may differ from its estimates. If actual results in the future vary from its estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The below table includes a rollforward of the deferred revenue contract liability balance for the three months ended March 31, 2022 and 2021.

	March 31, 2022	March 31, 2021
Beginning Balance	$ 1,585	1,172
Amounts deferred	4,406	2,252
Revenue recognized	(4,011)	(2,330)
Ending Balance	$ 1,980	1,094

Accounts Receivable, Net

Accounts receivables are stated at net realizable value. On a periodic basis, management evaluates its accounts receivable and determines whether to provide an allowance or if any accounts should be written off based on a past history of write-offs, collections and current credit conditions. A receivable is considered past due if the Company has not received payments based on agreed-upon terms. The Company generally does not require any security or collateral to support its receivables. The Company performs ongoing evaluations of its customers. The Company has recorded an allowance against its receivables of $0.2 million and $0.5 million as of March 31, 2022, and December 31, 2021, respectively.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”), or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company’s consolidated financial statements upon adoption. Under the Jumpstart Our Business Startups Act of 2012, as amended (the “JOBS Act”), the Company meets the definition of an emerging growth company and has elected the extended transition period for complying with certain new or revised accounting standards pursuant to Section 107(b) of the JOBS Act.

In February 2016, the FASB issued Accounting Standards Update 2016-02, *Leases* (Topic 842) (“ASU 2016-02”). Under ASU 2016-02, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. For leases with a term of twelve months or less, the lessee is permitted to make an accounting policy election not to recognize lease assets and lease liabilities by class of underlying assets. The guidance is effective for the Company for annual periods beginning after December 15, 2021. Prior to adopting the new lease standard, the Company accounted for its leases in accordance with ASC 840, *Leases*.

The Company adopted the new standard on January 1, 2022 using a modified retrospective basis, which requires the Company to reflect its leases on its balance sheet for the earliest comparative period presented. As a result, prior periods are presented in accordance with the previous guidance in ASC 840. At contract inception, the Company determines if an arrangement is or contains a lease. A lease conveys the right to control the use of an identified asset for a period of time in exchange for consideration. If an arrangement is determined to be or contain a lease, the lease is assessed for classification as either an operating or finance lease at the lease commencement date, defined as the date on which the leased asset is made available for use by the Company, based on the economic characteristics of the lease. The Company has elected to apply the package of practical expedients, which allows entities to not reassess (i) whether an arrangement is or contains a lease, (ii) the classification of its leases, and (iii) the accounting for initial direct costs. Further, the Company has elected, by class of underlying asset, the short-term lease exception for leases with terms of twelve months or less. In doing so, the Company will not recognize a lease liability or right of use asset on its consolidated balance sheets for such short-term leases. Finally, the Company elected, by class of underlying asset, the practical expedient to not separate lease and non-lease components. As a result of the adoption of ASC 842, the Company has concluded that all of its leases are operating leases that meet the short-term lease exception, given the terms of the leases are twelve months or less. As a result, the Company has not recorded an operating lease liability or operating lease right of use asset. There was no impact to the Company’s results of operations and cash flows from operations.

3. Business Combination

On September 9, 2021, the business combination between Blue Water Merger Sub and Legacy Clarus, was consummated, pursuant to the Merger Agreement dated April 27, 2021 (the "Business Combination"). Upon the closing of the Business Combination, Merger Sub merged with and into Legacy Clarus, with Legacy Clarus as the surviving company in the Merger and becoming a wholly-owned subsidiary of the Company. Upon the closing of the Business Combination, Blue Water changed its name to "Clarus Therapeutics Holdings, Inc."

The Business Combination is accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, Blue Water is treated as the acquired company and Legacy Clarus is treated as the acquirer for financial statement reporting and accounting purposes. As a result, the historical operations of Legacy Clarus are deemed to be those of the Company. Therefore, the financial statements included in this report reflect (i) the historical operating results of Legacy Clarus prior to the Business Combination; (ii) the combined results of the Blue Water and Legacy Clarus following the Business Combination on September 9, 2021; (iii) the assets and liabilities of Legacy Clarus at their historical cost; and (iv) the Company's equity structure for all periods presented. The recapitalization of the number of shares of common stock attributable to the Business Combination is reflected retroactively to the earliest period presented and will be utilized for calculating earnings per share in all prior periods presented. No step-up basis of intangible assets or goodwill was recorded in the Business Combination consistent with the treatment of the transaction as a reverse recapitalization of Legacy Clarus.

The aggregate consideration issued or reserved for issuance to Legacy Clarus securityholders upon the closing of the Merger was 17,886,348 shares of Company common stock. The 17,886,348 shares includes an aggregate of 1,905,000 shares of common stock (which included the 405,000 shares of the Company's common stock that were allocated to the senior secured noteholders pursuant to the share allocation agreement, as described in Note 7, *Debt*, of which 270,000 shares reallocated to the senior secured note holders from Legacy Clarus's equity holders and 135,000 shares from the Blue Water founder that were transferred from the Sponsor), which were issued to the holders of Legacy Clarus' senior secured notes in connection with the Merger Agreement and were in exchange for $18.6 million of aggregate principal amount of the senior secured notes and certain outstanding royalty rights. Within the aggregate shares issued to Legacy Clarus securityholders is also 2,549,939 shares of common stock at $10.00 per share, that were issued to Legacy Clarus equity holders for the private placement additional closing shares, of which such noteholders provided gross proceeds of $25.0 million, from the date of Merger Agreement signature through Effective Time. Further, 4,901,564 shares of common stock were issued to the holders of the Series D Preferred Stock and 8,529,846 shares of common stock were issued to the holders of Legacy Clarus convertible notes that were issued and outstanding prior to the Effective Time.

In connection with the Business Combination, the Company incurred equity issuance costs and other costs considered direct and incremental to the transaction totaling $8.4 million, consisting of legal, accounting, and financial advisory and other professional fees. These amounts are reflected within additional paid in capital in the consolidated balance sheet as of December 31, 2021.

Summary of Net Proceeds

The following table summarizes the elements of the net proceeds from the Business Combination as of December 31, 2021 (in thousands):

Cash – Blue Water Trust Account and cash (net of redemptions)	$25,394
Less: Equity issuance costs and other costs paid	(8,385)
Net Proceeds from the Business Combination	$17,009

Summary of Shares Issued

Previously authorized, issued and outstanding shares of common stock of Legacy Clarus were cancelled and extinguished upon completion of the Business Combination. The following table summarizes the number of shares of common stock outstanding immediately following the consummation of the Business Combination:

Blue Water shares outstanding prior to the Business Combination	3,839,469
Conversion of Legacy Clarus Series D Preferred Stock	4,901,564
Conversion of Legacy Clarus convertible notes	8,529,846
Conversion of additional capital provided by Legacy Clarus convertible note and senior note holders	2,549,938
Conversion of Senior Secured Note principal and royalty rights	1,905,000
Total shares of the Company's common stock outstanding immediately following the Business Combination	21,725,817

4. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis:

	March 31, 2022			
(in thousands)	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents:				
Money market funds	$ 8,003	$ 8,003	$ —	$ —
Total assets	$ 8,003	$ 8,003	$ —	$ —
Liabilities				
Private placement warrant liability	$ 925	$ —	$ —	$ 925
Total Liabilities	$ 925	$ —	$ —	$ 925

	December 31, 2021			
(in thousands)	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents:				
Money market funds	$ 13,002	$ 13,002	$ —	$ —
Total assets	$ 13,002	$ 13,002	$ —	$ —
Liabilities				
Private placement warrant liability	$ 1,567	$ —	$ —	$ 1,567
Total Liabilities	$ 1,567	$ —	$ —	$ 1,567

During the three months ended March 31, 2022 and the year ended December 2021, there were no transfers or reclassification between levels of financial assets and financial liabilities.

As of March 31, 2022 and December 31, 2021, the Company's cash equivalents consisted of money market funds, classified as Level 1 financial assets, as these assets are valued using quoted market prices in active markets without any valuation adjustment.

As of March 31, 2022 and December 31, 2021, the Company had Level 3 financial liabilities that were measured at fair value on a recurring basis. The Company's Warrant Liabilities (defined below) are carried at fair value, determined using Level 3 inputs in the fair value hierarchy. As of March 31, 2022 the warrant liabilities were valued at $0.9 million, and as of December 31, 2021, the warrant liabilities were valued at $1.6 million.

The carrying amounts reported in the accompanying balance sheets for cash, accounts receivable, accounts payable and accrued expenses approximate their fair value based on the short-term nature of these instruments. The carrying value of long-term and short-term debt, taking into consideration debt discounts and related derivative instruments, is estimated to approximate fair value.

Warrant Liabilities

In conjunction with a previous loan agreement of Legacy Clarus that was fully paid in 2017, certain lenders were granted warrants (or the "Series D Warrants"), to purchase shares of Series D Preferred Stock. Series D Warrants that were outstanding immediately prior to the Effective Time were converted into warrants to purchase 9,246 shares of the Company's common stock at an exercise price of $29.74 per share and the expiration date remains April 9, 2023. Such warrants are liability classified in accordance with ASC 815.

At the Effective Time and immediately following the completion of the Business Combination, 9,195,000 warrants, including 5,750,000 IPO Warrants and 3,445,000 Private Placement warrants, previously issued by Blue Water, were assumed by the Company. Upon consummation of the Merger, the Company concluded that the IPO Warrants are equity classified and the Private Placement Warrants are liability classified in accordance with ASC 815.

The Private Placement Warrants are a freestanding financial instrument that requires the Company to transfer equity instruments upon exercise by the warrant holder at a strike price equal to $11.50 per share (the "Private Placement Warrant Liability"). The valuation of the Private Placement Warrant Liability was determined with the assistance of an independent valuation firm that used a modified Monte Carlo simulation model at inception, as the Private Placement Warrants were subject to a market-based redemption feature prior to the completion of the Business Combination. Following the completion of the Business Combination, the Private Placement Warrants were valued at each measurement date using the Black-Scholes model, as the exercise price was fixed at $11.50 per share and was no longer subject to the market-based redemption features. The fair value was determined using Level 3 inputs. The Private Placement Warrants to purchase common stock are remeasured at each reporting and settlement date. Changes in fair value for each reporting period are recognized in other income (expense) in the statements of operations. A change in the assumptions related to the valuation of the warrant liabilities could have a significant impact on the value of the obligation.

The following table sets forth a summary of the assumptions used to estimate the fair value of the warrant liabilities at March 31, 2022:

Fair value of underlying instrument	$1.49
Risk-free interest rate	2.43%
Expected term (in years)	4.44
Expected volatility	75.0%
Expected dividend yield	— %

The following table sets forth a summary of changes in the fair value of the warrant liabilities for the three months ended March 31, 2022 (in thousands):

Balance at December 31, 2021	$1,567
Change in fair value of warrant liability	(642)
Balance at March 31, 2022	$ 925

5. Inventory

Inventory consisted of the following as of March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Raw material	$ 6,688	$ 6,850
Work-in-process	469	1,452
Finished goods	16,360	14,500
Total inventory	23,517	22,802
Inventory reserve	(8,587)	(8,588)
Total inventory, net of reserve	$ 14,930	$ 14,214

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Selling and marketing costs	$ 9,310	$ 6,031
Employee compensation and related benefits	1,377	2,005
Professional fees	746	225
Total	$ 11,433	$ 8,261

7. Debt

Convertible Notes

From 2016 to 2021, Legacy Clarus issued several convertible notes (the "Convertible Notes") pursuant to which Legacy Clarus borrowed an aggregate of $82.3 million from existing investors and related parties. All Convertible Notes accrued interest at a rate of 8% compounded daily and had a maturity date of March 1, 2025. The Convertible Notes contained various conversion features. The Company recorded the notes at the original issuance price, net of the conversion feature discount. The conversion feature discount was accreted to the face value of the notes over the period from the issuance date until the conversion date, offset against interest expense.

At the Effective Time, all principal and accrued interest under Legacy Clarus' convertible notes immediately prior to the Effective Time converted into 8,529,846 shares of the Company's common stock. As such, there were no Convertible Notes outstanding on March 31, 2022 or December 31, 2021.

The Company determined that the acquisition premium and the qualified and non-qualified financing conversion features were embedded derivative instruments requiring bifurcation as separate liabilities with a corresponding debt discount. The debt discount was amortized to interest expense using the effective interest rate method over the term of the Convertible Notes. The Company recognized interest expense of $1.6 million related to the Convertible Notes during the three months ended March 31, 2021.

In March 2021, upon an investor's decision to not participate in the next round of Convertible Notes, pursuant to the Convertible Notes' provisions, $3.4 million of the investor's Convertible Notes converted into 747,451 shares of Series D Preferred Stock and such Series D Preferred Stock issued as a result of this conversion was converted into Legacy Clarus common stock. At the date of conversion, the outstanding principal and accrued interest on the Convertible Notes were $2.6 million and $0.8 million, respectively.

Senior Secured Notes

The carrying value of the Company's senior secured notes consisted of the following as of March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Principal amount	$ 43,125	$ 43,125
Accrued (prepaid) interest	(62)	4,354
Unamortized debt discount	(4,578)	(5,210)
Total	$ 38,485	$ 42,269

On March 12, 2020, Legacy Clarus issued and sold senior secured notes to certain lenders not related to the Company. The aggregate principal amount of the senior secured notes was $50.0 million and Legacy Clarus received $43.6 million in net proceeds after deducting transaction expenses of $3.5 million and prepaid interest of $2.9 million.

In the second quarter of 2021, Legacy Clarus added two additional notes to the principal senior secured notes balance, the PIK Note (as defined and further described below) and the Indenture Note (as defined and further described below), totaling $8.1 million. In the third quarter of 2021, the Company added one additional note to the principal senior secured notes balance, the Second Indenture Note (as defined and further described below), totaling $3.6 million.

As part of the Merger (as further described in Note 3, *Business Combination*), $10.0 million of the principal on the senior secured notes and certain royalty rights were exchanged for an 1,500,000 shares of the Company's common stock and converted at a price of $10.20 per share. Further, under a share allocation agreement entered into by Blue Water and Legacy Clarus on September 1, 2021, as part of the Merger, an additional 405,000 shares of the Company's common stock were allocated to the senior secured noteholders (which included 270,000 shares reallocated from Legacy Clarus's equity holders and 135,000 shares that were transferred from the Sponsor pursuant to the share allocation agreement). Further, an additional $5.0 million of the principal of the senior secured notes balance associated with the Indenture Note and $3.6 million of the principal of the senior secured notes balance associated with the Second Indenture Note, plus related accrued interest, were exchanged for an aggregate 882,318 shares of the Company's common stock, which converted at a price of $10.00 per share.

As a result of the exchange of the principal on the senior secured notes and certain royalty rights for shares of the Company's common stock at the Effective Time, the Company wrote off $18.6 million of principal associated with the senior secured notes, $1.5 million of the remaining unamortized debt discount associated with the senior secured notes, and the full carrying value of $11.5 million associated with royalty rights obligation. The Company recorded a gain of approximately $0.3 million as a result of the extinguishment, representing the difference between the carrying value of the debt exchanged and the value of the shares converted based on the conversion price at the closing of the Business Combination.

The senior secured notes bear interest at 12.5% and specify semiannual payments on March 1 and September 1 and have a maturity date of March 1, 2025. The first two years provide for interest-only payments with principal payment beginning in 2022. The senior secured notes are governed by an indenture, dated as of March 12, 2020, between Legacy Clarus and the investors. The interest rate will increase to 14.50% for overdue installments in the event of default. In addition to liquidation preference, the senior secured notes contain a lien on all assets of Legacy Clarus. The Company made an interest payment on the senior secured notes of $5.7 million during the three months ended March 31, 2022.

Future principal payments of the senior secured notes are as follows (in thousands):

Years ended December 31,	Amount
2022 (remaining 9 months)	$ 6,000
2023	15,125
2024	14,000
2025	8,000
Total	$43,125

The senior secured notes had a detachable royalty feature under which the lenders were to receive a royalty of 0.56% to 1.67% on net sales beginning in 2021, with the royalty obligation continuing until the lenders receive total royalty payments of approximately $24.2 million. The value assigned to royalty rights was recorded as a debt discount to the Notes and was amortized to interest expense over the life of the notes. For the three months ended March 31, 2021 the Company recorded $736 thousand of interest expense associated with the royalty rights. Pursuant to the Merger Agreement and conversion terms, the royalty obligation no longer exists.

During the three months ended March 31, 2022 and 2021, the Company recorded $2.0 million and $2.1 million, respectively, in interest expense on the senior secured notes, of which $0.6 million and $0.7 million, respectively, was non-cash interest expense associated with the amortization of the debt discount and issue costs. The Company made a cash interest payment of $5.7 million during the three months ended March 31, 2022, which was net of $190 thousand of prepaid interest. The Company did not make any cash interest payments during the three months ended March 31, 2021.

Pursuant to the indenture governing the senior secured notes, there are various covenants that limit the Company's ability to engage in specified types of transactions including selling, transferring, leasing, or disposing certain assets, encumbering or permitting liens on certain assets, making certain restricted payments, including paying dividends on, or repurchasing or making distributions with respect to common stock, and entering into certain transaction with affiliates. Also, pursuant to the indenture governing the senior secured notes, the Company is required to maintain a balance of not less than $8.0 million in cash and cash equivalents, calculated as of the last day of each calendar month.

The Company has classified the full carrying value of $38.5 million related to the senior secured notes as a current liability within the March 31, 2022 balance sheet as, if the Company is unable to obtain funding or generate operating cash flow, the Company does not expect that it will be in compliance with the covenants under the senior secured notes within one year of the balance sheet date. Refer to Note 1 for further disclosure related to the Company's assessment of the ability to operate as a going concern as of March 31, 2022.

PIK Note

In May 2021, Legacy Clarus entered into a payment-in-kind, or PIK, note (the "PIK Note"), in relation to its missed interest payment (which was due in March 2021) on its senior secured notes, pursuant to which Legacy Clarus borrowed an aggregate of $3.1 million from senior secured noteholders, to be included in the principal senior secured notes balance. The PIK Note accrues interest at a rate of 14.5%, compounded daily. Pursuant to the PIK Note, on February 1, 2023 the Company is required to make a payment of principal in the amount of $3.1 million, plus accrued and unpaid interest in respect of such principal. The principal amount due on the PIK note is included within the total principal balance of the senior secured notes of $43.1 million.

8. Stockholders' Equity (Deficit)

The condensed consolidated financial statements have been retroactively adjusted for all periods presented to reflect the Business Combination and reverse recapitalization as defined in Note 3, *Business Combination*.

Preferred Stock

Pursuant to the terms of the Amended and Restated Certificate of Incorporation dated September 9, 2021, the Company authorized 10,000,000 shares of preferred stock with a par value of $0.0001. The Company's Board of Directors has the authority, without further action by the stockholders, to issue such shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the designations, powers, voting, and other rights, preferences and privileges of the shares. There were no issued and outstanding shares of preferred stock as of March 31, 2022 or December 31, 2021.

In connection with the closing of the Business Combination (as described in Note 3), all previously issued and outstanding shares of Series A Preferred Stock, Series B Preferred Stock, and Series C Preferred Stock were cancelled and extinguished. Further, all previously issued and outstanding Series D Preferred Stock was cancelled and exchanged for 4,901,564 shares of the Company's common stock.

Common Stock

Pursuant to the terms of the Amended and Restated Certificate of Incorporation, the Company authorized 125,000,000 shares of common stock with a par value of $0.0001. As of March 31, 2022, there were 24,750,011 shares of common stock issued and outstanding.

Previously authorized, issued and outstanding shares common stock of Legacy Clarus were cancelled and extinguished upon completion of the Business Combination. For purposes of earnings per share for the three months ended March 31, 2021, the Company has retroactively adjusted the common shares issued and outstanding prior to September 9, 2021 to zero to give effect to the cancellation of Legacy Clarus common stock as a result of the conversion terms in the Merger Agreement.

Voting

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders.

Dividends

Common stockholders are entitled to receive dividends, as may be declared by the board of directors. No dividends have been declared to date.

Warrants

As disclosed in Note 4, in conjunction with a previous loan agreement of Legacy Clarus, the Company issued a warrant for 9,246 shares of the Company's common stock at an exercise price of $29.74 per share and the expiration date remains April 9, 2023. As of March 31, 2022, the warrant remains unexercised.

In December 2020, the Company consummated its IPO of 5,750,000 units (each unit representing a share of common stock and a warrant to purchase a share of common stock ("IPO Warrants")), at $10.00 per unit. Simultaneously with the closing of the IPO, the Company consummated the private placement ("Private Placement") of 3,445,000 warrants (each, a "Private Placement Warrant" and collectively, the "Private Placement Warrants") at a price of $1.00 per Private Placement Warrant to Blue Water Sponsor LLC.

The IPO Warrants and Private Placement Warrants became exercisable on the Closing Date of the Merger. The warrants have an exercise price of $11.50 per share, subject to adjustments, and will expire five years from the Closing Date. The Private Placement Warrants are identical to the IPO Warrants, except that the Private Placement Warrants and the shares of Class A common stock issuable upon exercise of the Private Placement Warrants will not be transferable, assignable or salable until the completion of a Business Combination, subject to certain limited exceptions. Additionally, the Private Placement Warrants will be non-redeemable so long as they are held by the Sponsor or their permitted transferees. As of March 31, 2022, there were 5,750,000 of the IPO Warrants and 3,445,000 of the Private Placement Warrants remain outstanding.

In December 2021, the Company issued and sold 3,024,194 units, in a private placement, at a purchase price of $4.96 per unit, resulting in net proceeds of $13.8 million, after deducting offering expenses. Each unit consisted of one share of common stock (or one pre-funded warrant in lieu thereof), and a five-year warrant to purchase one share of common stock at an exercise price of $5.25 per share. The exercise price and the number of shares of common stock issuable upon exercise of each warrant is subject to appropriate adjustments in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the Company's common stock. In connection with the private placement, the Company filed a resale registration statement with the SEC in December 2021 to register the resale of the common stock by the purchaser (including the shares of common stock underlying the pre-funded warrants and warrants) in the private placement. Upon issuance, the Company classified the warrants within equity in the consolidated balance sheet. On March 10, 2022, 724,194 pre-funded warrants issued as part of the private placement were exercised for a price of $0.00001 per share and were converted into shares of common stock. As of March 31, 2022, there were 3,024,194 warrants outstanding with an exercise price of $5.25 per share.

9. Stock-Based Compensation

Clarus Therapeutics Holdings, Inc. 2021 Stock Option and Equity Incentive Plan

On August 27, 2021, the Company's stockholders approved the Clarus Therapeutics Holdings, Inc. 2021 Stock Option and Equity Incentive Plan (the "2021 Plan"). The 2021 Plan provides for the Company to make equity and equity-based incentive awards to officers, employees, directors and consultants. Pursuant to the 2021 Plan, an initial 3,475,000 shares of the Company's common stock were reserved for issuance (the "Initial Limit"). The 2021 Plan provides that the shares reserved and available for issuance under the 2021 Plan will automatically increase each January 1, beginning on January 1, 2022, by 4% of the outstanding number of shares of common stock on the immediately preceding December 31, or such lesser amount as determined by the plan administrator (the "Annual Increase"). Accordingly, on January 1, 2022, 961,033 shares were added to the number of shares reserved and available for issuance under the 2021 Plan. As of March 31, 2022, there were 1,172,550 options and 468,020 restricted stock units granted under the 2021 Plan. As of March 31, 2022, there are 4,436,033 shares authorized and 2,795,463 shares remaining available for grant under the 2021 Plan.

Clarus Therapeutics Holdings, Inc. Employee Stock Purchase Plan

On August 12, 2021, the Company's stockholders approved the Clarus Therapeutics Holdings, Inc. Employee Stock Purchase Plan (the "ESPP"). An aggregate of 347,500 shares were reserved and available for issuance under the 2021 ESPP. The 2021 ESPP provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by the lesser of 347,500 shares of the Company's common stock, 1.0% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31, or such lesser amount as determined by the ESPP administrator. Accordingly, on January 1, 2022, 240,258 shares were added to the number of shares reserved and available for issuance under the ESPP. As of March 31, 2022, the Company had not issued any shares under the ESPP. As of March 31, 2022, there are 587,758 shares authorized and available for grant under the ESPP.

Stock Options

Stock options typically vest over three years and have a maximum term of 10 years. The Company typically grants stock options to employees and non-employees at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant.

The Company utilized the Black-Scholes option-pricing model to estimate the fair value of stock options awarded to employees. The Black-Scholes option-pricing model requires several key assumptions. The key assumptions used to apply this pricing model were as follows:

	Three Months Ended March 31, 2022
Risk free interest rate	2.38%
Expected term (in years)	6.08
Expected dividend yield	0%
Expected volatility of underlying common stock	77.07%

The following table summarizes stock option activity under the 2021 Plan:

	Number of options	Weighted average exercise price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
Outstanding as of December 31, 2021	1,083,550	$ 4.78	9.95	$ —
Granted	125,000	1.31		
Exercised	—	—		
Cancelled or forfeited	(36,000)	4.78		
Outstanding as of March 31, 2022	1,172,550	$ 4.62	9.74	$ 23
Options vested and exercisable as of March 31, 2022	—	$ —	—	$ —

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the common stock as of the end of the reporting period. The weighted average grant-date fair value of stock options granted during the three months ended March 31, 2022 was $0.89 per share.

Restricted Common Stock

The Company has granted restricted common stock with service-based vesting conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder, except for transfers for estate planning purposes in which the transferee agrees to remain bound by all restrictions set forth in the original common stock purchase agreement. They are legally issued and outstanding but only accounted for as outstanding when vested. These restrictions lapse over the three-year vesting term of each award. The purchase price of each share of restricted common stock was $0.0001 per share.

A summary of the activity for the three months ended March 31, 2022 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock as of December 31, 2021	433,420	$ 4.78
Granted	49,000	1.31
Forfeited	(14,400)	4.78
Unvested restricted stock as of March 31, 2022	468,020	$ 4.42

The aggregate fair value of restricted common stock awards that vested during the three months ended March 31, 2022 was zero.

Legacy Clarus Stock Option and Incentive Plan

Legacy Clarus previously maintained various stock option and incentive plans and awarded options under such plans. Upon completion of the Business Combination, all such plans were terminated, and all options issued and outstanding, whether vested or unvested, were cancelled and extinguished. As a result, the Company recognized approximately $0.2 million of previously unrecognized stock-based compensation expense related to unvested stock options under the plans at the closing of the Business Combination.

Stock-Based Compensation Expense

Stock-based compensation expense is as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Selling and marketing	$ 99	$ 5
Research and development	31	16
General and administrative	302	155
Total stock-based compensation expense	$ 432	$ 176

As of March 31, 2022, there was $4.9 million of unrecognized stock-based compensation expense related to unvested stock and restricted common stock, which is estimated to be recognized over a period of 3.23 years.

10. Income Taxes

The Company did not record a federal or state or income tax provision or benefit for the three months ended March 31, 2022 or 2021 due to the expected loss before income taxes to be incurred, as well as the Company's continued maintenance of a full valuation allowance against its net deferred tax assets.

Under Internal Revenue Code Section 382, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss ("NOL") carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The Company has not completed a study to assess whether an "ownership change" has occurred or whether there have been multiple ownership changes since the Company became a "loss corporation" as defined in Section 382. Future changes in the Company's stock ownership, which may be outside of the Company's control, may trigger an "ownership change." In addition, future equity offerings or acquisitions that have equity as a component of the purchase price could result in an "ownership change." If an "ownership change" has occurred or does occur in the future, utilization of the NOL carryforwards or other tax attributes may be limited, which could potentially result in increased future tax liability to the Company.

11. License Agreements

Agreement with HavaH

In May 2021, Legacy Clarus entered into a license agreement (the "HavaH Agreement") with HavaH Therapeutics, or HavaH, an Australia-based biopharmaceutical company developing androgen therapies for inflammatory breast disease and certain forms of breast cancer. Under the HavaH Agreement, the Company will acquire the development and commercialization rights for HavaH T+Ai™, to be renamed CLAR-121.

Under the terms of the licensing agreement, HavaH may be eligible for up to $10.8 million in potential development and regulatory milestone payments. Additionally, HavaH would be eligible for royalty payments and up to $30.0 million in potential commercial milestones. Such royalty payments will be based on total aggregate annual net sales of CLAR-121 in the territory, at a low single digit percentage rate (when there is no patent protection or regulatory exclusivity) or a low teens percentage rate (where CLAR-121 has patent protection or regulatory exclusivity). Additionally, such royalties are payable until the later of ten years or the loss of patent protection or regulatory exclusivity.

To date, pursuant to the HavaH Agreement, the Company has made cash payments of $0.5 million consisting of the upfront payment.

Agreement with The Royal Institution for the Advancement of Learning/McGill University

In September 2021, the Company entered into a license agreement (the "McGill Agreement") with The Royal Institution for the Advancement of Learning/McGill University, or McGill, a Canadian University. Under the agreement, the Company will develop and commercialize McGill's proprietary technology designed to treat conditions associated with CoQ10 deficiencies in humans.

Under the terms of the licensing agreement, McGill may be eligible for up to $10.5 million in potential development and regulatory milestone payments. Additionally, McGill would be eligible for royalty payments and up to $15.0 million in potential commercial milestones. Such royalty payments will be based on total aggregate annual net sales of any licensed products that are covered by the licensed patents in the territory, at a low single digit percentage rate.

To date, pursuant to the McGill Agreement, the Company has made cash payments of $0.4 million consisting of the upfront payment.

12. Commitments and Contingencies

Lease Commitments

The Company leases office space in Northbrook, Illinois and Murfreesboro, Tennessee under non-cancelable operating leases that expire on December 31, 2022 and September 30, 2022, respectively. Total rent expense under the lease agreements was $0.1 million and $40 thousand for the three months ended March 31, 2022 and 2021, respectively. The future minimum lease payments required under the lease agreements through the remaining terms total $0.1 million.

Purchase Obligations

In July of 2009, Legacy Clarus entered into a commercial manufacturing agreement, as amended, with Catalent Pharma Solutions, LLC (the "Catalent Agreement"). Pursuant to the terms of the Catalent Agreement, the Company must make minimum annual purchases of JATENZO equal to 7.0 million softgels, through the initial term, or March 2025. Any shortfall between the minimum annual purchase quantities and actual purchases will be multiplied by a unit price, as defined in the Catalent Agreement, and paid to Catalent within 30 days of any year-end that the minimum purchase requirement is not met. The Company has not made any payments to Catalent as a result of a shortfall in minimum purchase quantities. The Catalent Agreement renews automatically for two-year periods and either party may terminate the contract upon twelve months written notice. Purchases under the Catalent Agreement were $1.2 million and $3.3 million during the three months ended March 31, 2022 and 2021, respectively.

The Company entered into a product supply agreement with Pharmacia & Upjohn Company LLC, or Pfizer (the "Pfizer Agreement"), effective January 1, 2021. Pursuant to the terms of the Pfizer Agreement, the Company must make minimum annual purchases of T-undecanoate equal to approximately $1.8 million per year, through the initial term, or January 2024. If there is a shortfall between the minimum annual purchase quantities and actual purchases, the difference between the minimum annual purchase amount and actual purchases will be paid to Pfizer by the Company. There were no purchases under the Pfizer Agreement during the three months ended March 31, 2022.

Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations.

On April 2, 2019, an action for patent infringement was filed against Legacy Clarus by Lipocine, Inc., or Lipocine, in the U.S. District Court for the District of Delaware. The lawsuit (Civil Action No. 19-cv-622, assigned to Judge William Bryson, U.S. Court of Appeals for the Federal Circuit, sitting by designation) sought a declaratory judgement of infringement under 35 U.S.C. § 271(a)-(c) arising from Legacy Clarus' intent to market and sell JATENZO, based on the FDA's approval of JATENZO in March 2019. Lipocine ultimately alleged that Legacy Clarus infringed certain claims in each of four U.S. Patents: U.S. Patent No. 9,034,858, U.S. Patent No. 9,205,057, U.S. Patent No. 9,480,690 and U.S. Patent No. 9,757,390. Lipocine sought monetary damages in the form of a reasonable royalty, pre-judgment interest, post-judgment interest, and attorneys' fees, costs and disbursements, and injunctive relief.

Legacy Clarus asserted defenses of noninfringement and invalidity under 35 U.S.C. §§ 103 and 112, and asserted counterclaims of inequitable conduct, patent misuse and exceptional case. Legacy Clarus's motion for summary judgment of invalidity under Section 112 was argued on January 15, 2021, and was granted on May 25, 2021, the decision finding all asserted claims invalid for failure to satisfy the written description requirement. On June 15, 2021, Legacy Clarus requested the Court to schedule a bench trial on Legacy Clarus's counterclaims of inequitable conduct, patent misuse, and exceptional case at the earliest practicable date, pursuant to the Court's invitation to make such a request.

In July 2021, Legacy Clarus and Lipocine entered into a settlement agreement that settled all claims between the parties, including a pending interference matter (No. 106,128) and the pending Legacy Clarus counterclaims against Lipocine, and provided for a payment by Lipocine to Legacy Clarus of a $4.0 million settlement fee payable as follows: $2.5 million upfront, $1.0 million within 12 months, and the remainder within two years. The Company is recognizing the payments in income as they are received. The Company received payment of $2.5 million of the $4.0 million in July 2021. On April 29, 2022, the Company entered into an amendment to the settlement agreement to reduce the remainder of the payments from $1.5 million to $1.3 million to be paid in a single installment on or before May 6, 2022, which has been received by the Company.

Pursuant to the settlement agreement, a joint stipulation for dismissal was filed, and was so ordered by the Court on July 15, 2021, thereby terminating the district court action. Moreover, and as part of this settlement, Lipocine filed a request for entry of an adverse judgment in Interference No. 106,128 on July 16, 2021. Judgment against Lipocine in Interference No. 106,128 was entered by the USPTO's Patent Trial and Appeal Board ("PTAB") on July 26, 2021. The Company believes that its U.S. Patent Application No. 16/656,178 involved in the interference may proceed to issuance due to entry of the decision adverse to Lipocine by the PTAB, but the '178 application has not issued to date.

13. Net Income (Loss) per Share

As a result of the Business Combination, all common stock of Legacy Claus was cancelled and terminated and shares of Series D Preferred Stock were converted to common stock of the Company. For purposes of presenting earnings per share, the shares and income (loss) per share related to Legacy Clarus's outstanding common stock prior to the Business Combination have been retroactively restated to zero, as all the Legacy Clarus common stock was cancelled. As a result, there is no loss per share, basic and diluted, for the three months ended March 31, 2021

The Company's potentially dilutive securities, which include preferred stock and stock options, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following shares from the computation of diluted net loss per share attributable to common stockholders as of March 31, 2022 and 2021 because including them would have had an anti-dilutive effect:

	March 31,	
	2022	2021
Redeemable convertible preferred stock	—	34,873,364
Convertible notes	—	18,550,825
Legacy Clarus warrants	9,246	183,438
IPO warrants	5,750,000	—
Private Placement warrants	3,445,000	—
PIPE warrants	3,024,194	—
Stock options and unvested restricted stock awards	1,640,570	—

14. Related Party Transactions

In July of 2020, a member of Legacy Clarus' board of directors, who is now a member of the Company's board of directors, temporarily expanded his director duties as an executive director, at the request of Legacy Clarus' board of directors. As executive director, this member received a total of $0.1 million in consulting fees during the three months ended March 31, 2021.

Upon completion of the Business Combination on September 9, 2021, the Company's senior secured note holders were given common stock in exchange for $10.0 million of principal on the senior secured notes and certain royalty rights, making certain senior secured note holders significant beneficial owners of the Company. As of March 31, 2022 the Company owed $43.1 million in principal and interest to the related party senior secured note holders and incurred $2.0 million in interest expense during the three months ended March 31, 2022.

15. Subsequent Events

On April 27, 2022 the Company issued and sold 27,270,720 Units (the "Offering"), consisting of (i) 26,680,720 shares of common stock, par value $0.0001, per share, and accompanying Class A warrants to purchase an aggregate of 26,680,720 shares of common stock, at a purchase price of $1.10 per common stock Unit and (ii) 590,000 pre-funded warrants to purchase 590,000 shares of common stock at an exercise price of $0.001 per pre-funded warrant, and accompanying Class A warrants to purchase an aggregate of 590,000 shares of common stock, at a purchase price of $1.10 (less) $0.001 per pre-funded warrant Unit, resulting in gross proceeds of approximately $30.0 million. The pre-funded warrants were exercised upon issuance and are no longer outstanding. Each Class A warrant is immediately exercisable for one share of common stock at an exercise price of $1.10 per share and expires five years after the issuance date. The Company received net proceeds of $27.9 million, after incurring transaction expenses of approximately $2.1 million.

On April 27, 2022, concurrent with the closing of the Offering, the Company issued warrants to acquire 1,300,000 shares of common stock to the accredited investor who purchased shares in the December 2021 private placement in exchange for a waiver of restrictions in its securities purchase agreement that prohibited the issuance of the Class A warrants with anti-dilution price protection terms. These warrants have a five-year term, an exercise price of $1.80 per share, and are subject to adjustment for dilutive issuances. The Company agreed to register for resale the shares underlying these warrants.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis provides information that our management believes is relevant to an assessment and understanding of our results of operations and financial condition. This discussion and analysis should be read together with our unaudited interim consolidated condensed financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q as well as our audited consolidated financial statements and notes thereto for the year ended December 31, 2021 and included in the 2021 Annual Report. In addition to historical financial information, this discussion contains forward-looking statements based upon our current expectations that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Our actual results could differ materially from such forward-looking statements as a result of various factors, including those set forth in Part I, Item 1.A under "Risk Factors" in the 2021 Annual Report and elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a pharmaceutical company focused on the commercialization of JATENZO, the first and only oral T-replacement, or T-replacement therapy of its kind that has received final approval by the FDA. We believe that current users of TRT are not satisfied with their current options and desire a therapeutic that is safe, effective and more convenient. Our primary goal for JATENZO is for it to become the preferred choice for TRT among men with hypogonadism — T deficiency accompanied by an associated medical condition. In parallel, our broader vision is to become a pharmaceutical company initially focused on the development and commercialization of T and metabolic therapies for men and women.

In March 2019, our first commercial product, JATENZO, was approved by the FDA as a TRT for the treatment of adult men with hypogonadism due to certain medical conditions. JATENZO is the first oral T therapy approved by the FDA in more than 60 years. JATENZO is a T-ester prodrug created by the linkage of T with the fatty acid undecanoic acid to form TU. Once absorbed, TU, an inactive version of T, is converted by natural enzymes in the body to bioactive T. In February 2020, we commenced U.S. commercial sales of JATENZO and, as of March 31, 2022, JATENZO was available under health plans representing approximately 72% of all covered lives in the United States. Of those lives, 76% of the commercial lives had access to JATENZO. For the three months ended March 31, 2022 and 2021, JATENZO generated net revenues of approximately $4.0 million, and $2.3 million, respectively, demonstrating consistent prescription and sales growth despite the commercial challenges presented by the ongoing COVID-19 pandemic. Total prescription growth for JATENZO for the three months ended March 31, 2022 increased 75% as compared to the prior year period. In August 2019, the FDA granted 3-year Hatch-Waxman market exclusivity to JATENZO, which prevented the FDA from granting full market approval to similar new drugs or generic competitors of JATENZO until March 27, 2022.

We continue to work on several life cycle management projects for JATENZO, including a label expansion to treat hypogonadal men with chronic kidney disease, development of a once-daily oral TU with Phase 2 clinical trial initiation anticipated in the second half of 2022, subject to availability of funding, and a label expansion to provide T therapy for female-to-male transgender individuals, with a Phase 4 clinical trial initiation anticipated in the second half of 2022, subject to availability of funding.

Since the beginning of our subsidiary's operations in 2004, we have focused primarily on developing and progressing JATENZO through clinical development, organizing and staffing, research and development activities, raising capital and commercial launch activities. We have one product approved for sale, JATENZO, as of March 31, 2022. Through March 31, 2022, we have received gross proceeds of $104.2 million from investors in our preferred stock, gross proceeds of $82.3 million from investors in our issued convertible debt, gross proceeds of $61.7 million from investors in issued senior secured notes and related royalty obligation, and net proceeds of $17.0 million from the closing of the business combination, and net proceeds of $13.8 million from investors in a December 2021 private placement. In April 2022, we closed an underwritten follow-on public offering raising approximately $27.9 million of net proceeds after deducting underwriting commissions and discounts and estimated offering expenses.

Merger

On September 9, 2021, we consummated the initial business combination pursuant to which Clarus Therapeutics, Inc. became our wholly-owned subsidiary and its equity holders and convertible debt holders equity interests converted into the right to receive shares of our common stock or else were canceled, retired and terminated without consideration. Upon the consummation of the business combination, we changed our name to "Clarus Therapeutics Holdings, Inc." See Note 1 to our unaudited interim condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for more information regarding the business combination.

The business combination was accounted for as a reverse recapitalization in accordance with U.S. generally accepted accounting principles. Under this method of accounting, we are treated as the acquired company and Clarus Therapeutics, Inc. is treated as the acquirer for financial statement reporting and accounting purposes. As a result, the historical operations of Clarus Therapeutics, Inc. are deemed to be our financial statements. Therefore, the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q reflect (i) the historical operating results of Clarus Therapeutics, Inc. prior to the business combination; (ii) the combined results following the business combination on the closing date; (iii) the assets and liabilities of Clarus Therapeutics, Inc. at their historical cost; and (iv) our equity structure for all periods presented. The recapitalization of the number of shares of common stock attributable to the business combination is reflected retroactively to the earliest period presented and will be utilized for calculating earnings per share in all prior periods presented. No step-up basis of intangible assets or goodwill was recorded in the business combination consistent with the treatment of the transaction as a reverse recapitalization of Clarus Therapeutics, Inc.

Risks and Liquidity

Since inception, we have incurred significant operating losses and have experienced negative operating cash flows. For the three months ended March 31, 2022 our net loss was $14.9 million. As of March 31, 2022, we had an accumulated deficit of $336.5 million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future if and as we:

- continue to commercialize JATENZO in the United States for the treatment of adult males with a deficiency or absence of endogenous T;
- incur sales and marketing costs to support the commercialization of JATENZO;
- incur contractual manufacturing costs for JATENZO;
- implement post-approval requirements related to JATENZO;
- actively pursue additional indications and line extensions for JATENZO for the treatment of adult males with a deficiency or absence of endogenous T;
- seek to attract and retain new and existing skilled personnel;
- invest in measures to protect and expand our intellectual property;
- seek to discover and develop additional product candidates;
- seek to in-license or acquire additional product candidates for other medical conditions;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- create additional infrastructure to support operations as a public company and incur increased legal, accounting, investor relations and other expenses; and
- experience delays or encounter issues with additional outbreaks of the pandemic in addition to any of the above.

We expect to incur significant expenses related to developing an internal commercialization capability to support product sales, marketing and distribution. Furthermore, we now expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of private and public equity offerings, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, existing ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our equity holders. Private and public equity offerings and debt financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations or other strategic transactions with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the commercialization efforts of our product, JATENZO, and/or any product portfolio expansion.

Because of the numerous risks and uncertainties associated with being a commercial stage pharmaceutical company and our efforts to grow our business by means of product and business development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. We began product sales in 2020, and if we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue operations at planned levels and be forced to reduce or terminate our operations.

In light of our current liquidity, we need to raise additional capital to support our operations and debt obligations and concurrently, we are exploring strategic alternatives for the purpose of maximizing stockholder value. We expect to devote significant efforts to raise capital, restructure our indebtedness and identify and evaluate potential strategic alternatives but there can be no assurance that these efforts will be successful, that we will be able to raise necessary capital on acceptable terms, reach agreement with our lenders, or that the strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. Our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of

action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders. Any failure in these efforts could force us to delay, limit or terminate our operations, make reductions in our workforce, discontinue our commercialization efforts for JATENZO as well as other development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, fall into forbearance on our debt obligations, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

These factors raise substantial doubt about our ability to continue as a going concern. Management believes that our existing cash and cash equivalents of $9.1 million as of March 31, 2022, the $27.9 million of net proceeds from our April 2022 public offering along with revenue generated from sales of JATENZO will fund our operating expenses and capital expenditure requirements into September 2022. See "— *Liquidity and Capital Resources*."

COVID-19 Business Update

The business disruptions associated with the ongoing COVID-19 pandemic had a significant negative impact on our financial statements for the three months ended March 31, 2022 and 2021. Management expects that the public health actions being undertaken to reduce the spread of the virus, and that will have to be undertaken again in the event the COVID-19 pandemic worsens, such as by the omicron variant or other variants that may surface, will create significant disruptions to us with respect to: (i) the demand for our products, (ii) the ability of our sales representatives to reach healthcare customers, (iii) our ability to maintain staffing levels to support our operations, (iv) our ability to continue to manufacture certain of our products, (v) the reliability of our supply chain and (vi) our ability to achieve the financial covenants required by the senior secured notes agreement. The extent to which the ongoing COVID-19 pandemic will impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, vaccinates rates and mandates, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We are closely monitoring the evolving impact of the pandemic on all aspects of our business. We have implemented a number of measures designed to protect the health and safety of our employees, support its customers and promote business continuity. We are also actively reviewing and implementing cost-saving measures including discontinuing or delaying all non-essential services and programs and instituting controls on travel, events, marketing and pre-clinical studies and clinical trials to adapt the business plan for the evolving COVID-19 challenges.

We expect to have an adequate supply of JATENZO through the end of 2022. We are working closely with our third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to product supplies as a result of the COVID-19 pandemic.

Components of Our Results of Operations

Product Revenue

Our subsidiary did not generate any product revenue from inception until 2020. Our first commercial product, JATENZO, was approved by the FDA as a treatment for adult males with a deficiency or absence of endogenous testosterone, in March 2019 and became commercially available in February 2020.

Total revenue consists of net sales of JATENZO. Net sales represent the gross sales of JATENZO less provisions for product sales discounts and allowances. These provisions include trade allowances, rebates to government and commercial entities, copay costs and other customary sales discounts. Although we expect net sales to increase over time, the provisions for product sales discounts and allowances may fluctuate based on the mix of sales to different customer segments and/or changes in accrual estimates. For further discussion of the components of revenue see "— *Critical Accounting Policies and Significant Judgments and Estimates*" included in the 2021 Form 10-K.

Cost of Product Sales

Cost of product sales include manufacturing and distribution costs, the cost of drug substance, royalties due to third parties on net product sales, freight, shipping, handling, storage costs, salaries of employees involved with production, and a reserve for short-dated, obsolete inventory. We began capitalizing inventory upon FDA approval of JATENZO.

We expect that our cost of product sales will increase moderately in the near term as we ramp up production to meet anticipated demand for JATENZO.

The shelf life of JATENZO is 30 months from the date of manufacture. Due to the low rate of inventory turnover generated by our commercial launch efforts for JATENZO during a global pandemic, we have a reserve for inventory obsolescence of $8.6 million as of March 31, 2022 and December 31, 2021. We will continue to assess obsolescence in future periods as demand for JATENZO and the rate of inventory turnover evolves.

Operating Expenses

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of commercialization expenses related to JATENZO, commercially launched in February of 2020, and FDA program fees. Prior to the commercial launch, we had significantly lower sales and marketing expenses. We anticipate that our sales and marketing expenses will increase in 2022 as we continue to expand our commercialization of JATENZO.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, such as salaries, stock-based compensation, benefits and travel expenses for personnel in executive, legal, finance and accounting, human resources, and other administrative departments. General and administrative expenses also consist of office leases, and professional fees, including legal, tax and accounting and consulting fees.

We anticipate that our general and administrative expenses will increase in the future to support continued commercialization efforts, ongoing and future potential research and development activities, and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees paid to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of Nasdaq and the SEC, insurance and investor relations costs.

Research and Development Expenses

Research and development expenses have primarily been limited to clinical trials, and chemistry, manufacturing, and controls, or CMC, and CMC activities related to JATENZO. Our research and development costs as incurred, include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- post-marketing requirements of the FDA for JATENZO and pharmaceutical development expense related to our internally -in-licensed products; and
- costs of outside consultants, including their fees and related travel expenses engaged in research and development functions.

We currently have one product, JATENZO, and do not currently track internal research and development expenses on an indication-by-indication basis as they primarily relate to personnel, early research and consumable costs, which are deployed across multiple programs. A significant portion of research and development costs are external costs, such as fees paid to consultants, central laboratories, contractors, contract manufacturing organizations, contract research organizations and companies that manufacture clinical trial materials and potential future commercial supplies. Inventory acquired prior to receipt of the marketing approval of JATENZO was recorded as research and development expense as incurred. We began capitalizing the costs associated with the production of JATENZO after the FDA approval in March 2019.

Our research and development expenses are expected to increase in the foreseeable future. Specifically, our costs will increase as we conduct additional clinical trials for JATENZO and conduct further developmental activities for our research and development pipeline programs.

Total Other Income (Expense), Net

Change in Fair Value of Warrant Liability and Derivative Liability

Subsequent to the completion of the merger, the change in fair value of the warrant liability relates to the change in fair value of the private placement warrant liabilities, which relate to warrants issued in a private placement concurrent with Blue Water’s IPO. The total change in fair value of the private placement warrants recorded during the three months ended March 31, 2022 was $0.6 million.

Interest Income

Interest income related to our operating bank accounts, including money market funds.

Interest Expense

Interest expense is related to our subsidiary’s convertible notes, senior secured notes and debt discount amortization.

Results of Operations

Comparison of the three months ended March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,			
	2022	2021	Change ($)	Change (%)
Net product revenue	$ 4,011	$ 2,330	$ 1,681	72%
Cost of product sales	664	367	297	81%
Gross profit	3,347	1,963	1,384	71%
Operating expenses:				
Sales and marketing	10,729	7,937	2,792	35%
General and administrative	5,285	3,605	1,680	47%
Research and development	881	1,210	(329)	(27%)
Loss from operations	(13,548)	(10,789)	(2,759)	26%
Other expense, net:				
Change in fair value of warrant liability and derivative, net	642	—	642	100%
Interest income	1	—	1	100%
Interest expense	(1,965)	(4,640)	2,675	(58%)
Total other expense, net	(1,322)	(4,640)	3,318	(72%)
Net loss	$(14,870)	$(15,429)	$ 559	(4%)

Net Product Revenue

For the three months ended March 31, 2022, we recorded $4.0 million of net product revenue, which increased by $1.7 million from $2.3 million for the three months ended March 31, 2021. The increase in net revenue is related to the growth of the brand through our sales and marketing efforts. We did not begin commercially selling JATENZO within the United States until February 2020, following FDA approval in March 2019.

Cost of Product Sales

Cost of product sales was $0.7 million for the three months ended March 31, 2022, which increased by $0.3 million, from $0.4 million for the three months ended March 31, 2021. The increase in cost of product sales is primarily due to increased product revenue sales.

Sales and Marketing Expenses

Sales and marketing expenses were $10.7 million for the three months ended March 31, 2022, which increased by $2.8 million, from $7.9 million for the three months ended March 31, 2021. The increase in sales and marketing expenses was primarily attributable to the following:

- a $2.0 million increase in outsourced advertising and promotion costs due to timing of media buys and agency activities;
- a $0.6 million increase in patient assistance costs;
- a $0.6 million increase in other sales and marketing related costs; offset by
- a $0.5 million decrease in commercial analytic and market research costs, primarily related to prescription and payor data.

General and Administrative Expenses

General and administrative expenses were $5.3 million for the three months ended March 31, 2022, which increased by $1.7 million, from $3.6 million for the three months ended March 31, 2021. The increase in general and administrative expenses was primarily attributable to the following:

- a $1.6 million increase in personnel costs, including stock-based compensation expense, primarily due to an increase in headcount and external consultants;
- a $0.5 million increase in insurance fees, related to directors' and officers' insurance;
- a $0.2 million increase in other general and administrative costs; offset by
- a $0.6 million decrease in consulting and professional fees.

Research and Development Expenses

Research and development expenses were $0.9 million for the three months ended March 31, 2022, which decreased by $0.3 million from $1.2 million for the three months ended March 31, 2021. The decrease in research and development expenses was primarily attributable to the following:

- a $0.7 million decrease in clinical costs related to costs incurred as part of the Phase 4 trials related to the development of JATENZO, our lead commercial product, during the three months ended March 31, 2021; offset by
- a $0.4 million increase in personnel costs.

Other Expense, Net

Total other expense, net was $1.3 million for the three months ended March 31, 2022, compared to $4.6 million for the three months ended March 31, 2021. The decrease of $3.3 million was primarily related to a $2.7 million decrease in interest expense and a $0.6 million increase in the change in fair value of the warrant liability and derivative.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, our subsidiary has incurred significant operating losses, has experienced negative operating cash flows and has accumulated significant accrued liabilities. Our net loss was $14.9 million for the three months ended March 31, 2022. As of March 31, 2022, we had cash and cash equivalents of $9.1 million and an accumulated deficit of $336.5 million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future. As a result, even with proceeds from the merger and our December private placement and April 2022 underwritten follow-on public offering, we will need substantial additional funding to support our continuing operations, service our indebtedness and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of private and public equity offerings, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions.

We are exploring strategic alternatives for the purpose of maximizing stockholder value. We expect to devote significant efforts to raise capital, restructure our indebtedness and identify and evaluate potential strategic alternatives but there can be no assurance that these efforts will be successful, that we will be able to raise necessary capital on acceptable terms, reach agreement with our lenders, or that the strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. Our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders. Any failure in these efforts could force us to delay, limit or terminate our operations, make reductions in our workforce, discontinue our commercialization efforts for JATENZO as well as other development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

April 2022 Underwritten Public Offering

On April 27, 2022, we issued and sold 27,270,720 Units in an underwritten public offering, consisting of (i) 26,680,720 shares of common stock, par value $0.0001, per share, and accompanying Class A warrants to purchase an aggregate of 26,680,720 shares of common stock, at a purchase price of $1.10 per common stock Unit and (ii) 590,000 pre-funded warrants to purchase 590,000 shares of common stock at an exercise price of $0.001 per pre-funded warrant, and accompanying Class A warrants to purchase an aggregate of 590,000 shares of common stock, at a purchase price of $1.10 (less) $0.001 per pre-funded warrant Unit, resulting in gross proceeds of approximately $30.0 million. The pre-funded warrants were exercised upon issuance and are no longer outstanding. Each Class A warrant is immediately exercisable for one share of common stock at an exercise price of $1.10 per share and expires five years after the issuance date. We received net proceeds of $27.9 million, after incurring transaction expenses of approximately $2.1 million.

On April 27, 2022, concurrent with the closing of the offering, we issued warrants to acquire 1,300,000 shares of common stock to the accredited investor who purchased shares in the December 2021 private placement in exchange for a waiver of restrictions in its securities purchase agreement that prohibited the issuance of the Class A warrants with anti-dilution price protection terms. These warrants have a five-year term, an exercise price of $1.80 per share, and are subject to adjustment for dilutive issuances. We agreed to register for resale of the shares underlying these warrants.

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net cash used in operating activities	$(17,268)	$(7,042)
Net cash used in investing activities	(10)	(11)
Net cash provided by financing activities	—	7,184
Net (decrease) increase in cash and cash equivalents	$(17,278)	$ 131

Operating Activities

Net cash used in operating activities was $17.3 million for the three months ended March 31, 2022, reflecting net loss of $14.9 million and non-cash charges of $4.0 million, offset by a net change of $1.6 million in net operating assets. The non-cash charges primarily consist of non-cash interest expense on debt financings and the royalty obligation, a change in the fair value of warranty liability, stock-based compensation expense and depreciation. The change in net operating assets and liabilities was primarily due to an increase in accounts receivable of $1.7 million, an increase in inventory of $0.7 million, partially offset by an increase in accrued expenses of $3.2 million, an increase in deferred revenue of $0.4 million, a decrease in prepaid expenses of $0.3 million, and an increase in accounts payable of $0.1 million.

Net cash used in operating activities was $7.0 million for the three months ended March 31, 2021, reflecting net loss of $15.4 million, offset by a net change of $3.6 million in net operating assets and non-cash charges of $4.8 million. The non-cash charges primarily consist of non-cash interest expense on debt financings and the royalty obligation, stock-based compensation expense and depreciation. The change in net operating assets and liabilities was primarily due to an increase in inventory of $2.2 million, an increase in accounts receivable of $0.8 million, an increase in prepaid expenses and other current assets of $0.3 million, partially offset by an increase in accounts payable of $4.1 million and an increase in accrued expenses of $2.8 million.

Investing Activities

During the three months ended March 31, 2022 and 2021, net cash used in investing activities was approximately $10 thousand and $11 thousand, respectively, for purchases of property and equipment.

Financing Activities

During the three months ended March 31, 2021, net cash provided by financing activities was $7.2 million, related to $7.2 million of proceeds from the issuance of convertible notes.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily related to our selling and marketing activities associated with the commercialization of JATENZO and our research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses. Until such time, if ever, we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. Our ability to raise additional capital may be adversely impacted by, but not limited to, potential worsening global economic conditions and our stock price, and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic, and more recently the Russian invasion of Ukraine. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests of existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If funding permits, we expect our expenses to increase substantially in connection with its ongoing activities, particularly as we advance the commercialization of our product JATENZO. In addition, we now expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company

Going Concern

We evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued.

Since inception, our subsidiary has devoted substantially all its efforts to business planning, clinical development, commercial planning and raising capital. Our subsidiary, and since the merger, we, have incurred significant losses from operations since inception and has an accumulated deficit of $336.5 million as of March 31, 2022. Further, as of March 31, 2022, we had a working capital deficit of $29.5 million.

In addition to the consummation of the merger and the related investment, we plan to seek additional funding through the expansion of our commercial efforts to grow JATENZO and our operating cash flow, business development efforts to out-license JATENZO internationally, equity financings, debt financings such as the secured notes described in Note 7, *Debt*, in the Notes to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q or other capital sources including collaborations with other companies or other strategic arrangements with third parties. There can be no assurance that these future financing efforts will be successful.

If we are unable to obtain funding or generate operating cash flow, we will be forced to delay, reduce or eliminate some or all of our product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all. The terms of any financing may adversely affect the holdings or the rights of our stockholders.

Based on our recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance our future operations, as of the issuance date of the condensed consolidated financial statements for the three months ended March 31, 2022, we have concluded that our cash and cash equivalents as of March 31, 2022 along with the proceeds from our April 2022 underwritten public offering will be sufficient to fund our operating expenses and capital expenditure requirements into September 2022. Accordingly, there is substantial doubt about our ability to continue as a going concern.

If we are unable to obtain funding or generate operating cash flow, we will be forced to delay, reduce or eliminate some or all of our product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all. The terms of any financing may adversely affect the holdings or the rights of our stockholders.

Working Capital

Because of the numerous risks and uncertainties associated with research, development and commercialization of JATENZO and our research and development portfolio, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- The costs, timing and ability to manufacture JATENZO;
- the costs of future activities, including product sales, marketing, manufacturing and distribution of JATENZO;
- the costs of manufacturing commercial-grade product and necessary inventory to support continued commercial launch;
- the costs of potential milestones related to license agreements;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue from commercial sale of its products;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, expanding and enforcing its intellectual property rights and defending intellectual property-related claims; and
- our ability to establish and maintain collaborations on favorable terms, if at all.

Material Cash Requirements from Contractual and Other Obligations

Purchase Obligations

We have an agreement with Catalent under which we must make minimum annual purchases of JATENZO softgel capsules, through March 2025. Any shortfall between the minimum annual purchase quantities and actual purchases will be multiplied by a unit price, as defined in such agreement, and paid to Catalent within 30 days of any year-end that the minimum purchase requirement is not met. We have not made any payments to Catalent as a result of a shortfall in minimum purchase quantities. Purchases under the Catalent Agreement for the three months ended March 31, 2022 and 2021 were $1.2 million and $3.3 million, respectively. The aggregate amount of future purchase obligations under the Catalent Agreement total $10 million as of March 31, 2022, of which $3.6 million is to be paid within one year.

We have an agreement with Pfizer, under which we must make minimum annual purchases of TU equal to approximately $1.8 million per year through January 2024. If there is a shortfall between the minimum annual purchase quantities and actual purchases, the difference between the minimum annual purchase amount and actual purchases will be paid to Pfizer. There were no purchases under the Pfizer Agreement during the three months ended March 31, 2022. The aggregate amount of future purchase obligations under the Pfizer Agreement total $4.7 million as of March 31, 2022, of which $1.8 million is to be paid within one year.

Lease Commitments

We have entered operating leases for rental space in Northbrook, Illinois and Murfreesboro, Tennessee that extend to December 31, 2022 and September 30, 2022, respectively. Total minimum rental payments owed under the leases as of March 31, 2022 totaled $99 thousand and are all due within one year.

We enter into contracts in the normal course of business with clinical trial sites, clinical and commercial supply manufacturers, and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts.

Long-Term Debt Commitments

As discussed above and in Note 7, *Debt*, to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, we have outstanding senior secured notes.

License Agreement Commitments

Under the terms of our licensing agreement with HavaH, we made an upfront payment of $0.5 million and HavaH may be eligible for up to $10.8 million in potential development and regulatory milestone payments. Additionally, HavaH would be eligible for royalty payments and up to $30.0 million in potential commercial milestones. Such royalty payments will be based on total aggregate annual net sales of CLAR-121 in the territory, at a low single digit percentage rate (when there is no patent protection or regulatory exclusivity) or a low teens percentage rate (where CLAR-121 has patent protection or regulatory exclusivity). Additionally, such royalties are payable until the later of ten years or the loss of patent protection or regulatory exclusivity. To date, pursuant to the HavaH Agreement, we have made cash payments of $0.5 million consisting of the upfront payment.

Under the terms of our licensing agreement with McGill, McGill may be eligible for up to $10.5 million in potential development and regulatory milestone payments. Additionally, McGill would be eligible for royalty payments and up to $15.0 million in potential commercial milestones. Such royalty payments will be based on total aggregate annual net sales of any licensed products that are covered by the licensed patents in the territory, at a low single digit percentage rate. To date, pursuant to the McGill Agreement, we have made cash payments of $0.4 million consisting of the upfront payment.

Critical Accounting Policies and Significant Judgments and Estimates

There have been no significant changes to our critical accounting policies from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” disclosed in our most recent annual financial statements included in the 2021 Annual Report.

Emerging Growth Company Status

We are an “emerging growth company” as defined in the Jobs Act and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company under Section 107 of the JOBS Act, which provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We elected to avail ourselves of the extended transition period and, therefore, while we are an emerging growth company, we will not be subject to new or revised accounting standards the same time that they become applicable to other public companies that are not emerging growth companies, unless we choose to early adopt a new or revised accounting standard.

Recently Issued Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements for the three months ended March 31, 2022 included elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks in the ordinary course of its business. Market risk represents the risk of loss that may impact its financial position due to adverse changes in financial market prices and rates. Our market risk exposure primarily relates to changes in interest rates.

Interest Rate Risk

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents are in the form of money market funds and our long-term debt financings. As of March 31, 2022 and December 31, 2021, we had cash and cash equivalents of $9.1 million and $26.4 million, respectively. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

As of March 31, 2022 and December 31, 2021, $43.1 million in aggregate principal amount of our outstanding debt obligations were at fixed interest rates, representing approximately 100% of our total debt, on an amortized cost basis. As of March 31, 2022 and December 31, 2021, our outstanding debt obligations at fixed interest rates were comprised of senior notes.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures as defined in Rules 13a15(e) and 15d-15(e) under the Exchange Act. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2022, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were not effective at the reasonable assurance level given the existence of the material weaknesses in our internal control over financial reporting discussed below.

In connection with the audit of our financial statements for the year ended December 31, 2021, we identified material weaknesses relating to (i) insufficient supervision and review, (ii) a lack of segregation of duties and (iii) a lack of access and input controls related to its financial reporting systems. Management believes these deficiencies are the result of a lack of accounting personnel to provide the necessary segregation and review.

We are committed and are taking steps necessary to remediate the control deficiencies that constituted the above material weakness by implementing changes to our internal control over financial reporting. We have started the process of remediating these deficiencies and will continue to take initiatives to improve our internal control over financial reporting and disclosure controls. Towards this end, we are in the process of hiring additional accounting personnel. Management believes these efforts will address the issues that led to the aforementioned deficiencies. We are committed to appropriately staffing the accounting and reporting functions. However, the implementation of these initiatives is not complete and may not fully address the material weaknesses in our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

Other than remediation activities to address the material weaknesses in our internal control over financial reporting discussed above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, in the ordinary course of business, we are subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. We are not currently party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors

Not applicable.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
31.1	Certification of Chief Executive Officer (Principal Executive Officer) Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer (Principal Financial and Accounting Officer) Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer (Principal Executive Officer) Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer (Principal Financial and Accounting Officer) Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* The certifications furnished in Exhibit 32.1 and 32.2 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 16, 2022

By: /s/ Robert E. Dudley
Name: Robert E. Dudley
Title: Chief Executive Officer
(Principal Executive Officer)

By: /s/ Richard Peterson
Name: Richard Peterson
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)